

PATENT  
Attorney Docket No. 056291-5230-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Nicola F. BATEMAN *et al.*

Application No.: 10/565,100

Filed: January 19, 2006

For: PHARMACEUTICAL COMPOSITION

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Group Art Unit: *Unassigned*

Examiner: *Unassigned*

Date: August 4, 2006

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Window, Mail Stop Amendment  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

**INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants petition the Examiner to consider this Information Disclosure Statement and documents listed on the attached Form PTO-1449. To the best of the undersigned's knowledge, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced Application. Accordingly, Applicants do not believe a fee is due for filing this Information Disclosure Statement.

With the exception of U.S. Patents and Publications, copies of the listed documents are attached. Applicants respectfully request that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

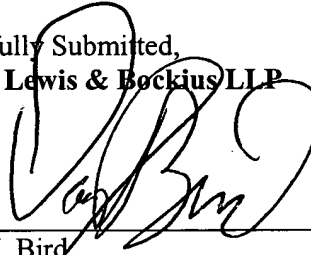
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a

**CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R.

§1.136(a)(3).

Respectfully Submitted,  
Morgan Lewis & Bockius LLP

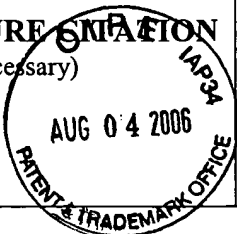


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<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				Attorney Docket No. <b>056291-5230-US</b>		Application No. <b>10/565,100</b>	
PTO Form 1449 August 4, 2006				Applicants: <b>Nicola F. BATEMAN et al.</b>			
Filing Date: <b>January 19, 2006</b>				Group Art Unit: <b>Unassigned</b>			



U.S. PATENT DOCUMENTS							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date
	1.	20020009494	January 24, 2002	Curatolo et al.	424	489	January 26, 2001
	2.	20020177601	November 28, 2002	Himmelsbach et al.	514	266.2	August 23, 2001
	3.	20030045537	March 6, 2003	Lee et al.	514	267	March 11, 2002
	4.	20050209229	September 22, 2005	Gilday et al.	514	234.2	May 23, 2005
	5.	3,608,063	September 21, 1971	Banker	424	485	August 15, 1969
	6.	4,178,376	December 11, 1979	Higuchi et al.	514	311	January 21, 1977
	7.	4,344,934	August 17, 1982	Martin et al.	514	462	February 21, 1980
	8.	4,704,284	November 3, 1987	Beatty et al.	424	469	August 12, 1982
	9.	5,457,105	October 10, 1995	Barker	514	234.5	August 2, 1994
	10.	5,559,158	September 24, 1996	Al-Razzak et al.	514	616	August 31, 1994
	11.	5,610,193	March 11, 1997	Al-Razzak et al.	514	616	May 22, 1996
	12.	5,616,582	April 1, 1997	Barker	514	234.5	June 15, 1995
	13.	5,631,248	May 20, 1997	Davis et al.	514	179	October 7, 1994
	14.	6,248,771	June 19, 2001	Shenoy et al.	514	418	March 4, 1998
	15.	6,294,192	September 25, 2001	Patel et al.	424	451	February 26, 1999
	16.	6,383,471	May 7, 2002	Chen et al.	424	45	April 6, 1999

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		Document No.	Date	Country	Class	Sub-Class	Translation
	17.	DE 3233764	May 7, 1987	Germany			Yes
	18.	EP 103387	March 21, 1984	EPA			
	19.	EP 640341	March 1, 1995	EPA			
	20.	EP 901786	March 17, 1999	EPA			
	21.	EP 1027886	August 16, 2000	EPA			
	22.	EP 1027887	August 16, 2000	EPA			
	23.	EP 1027888	August 16, 2000	EPA			
	24.	GB 1278816	June 21, 1972	Great Britain			
	25.	GB 2306885	May 14, 1997	Great Britain			
	26.	JP 05-255066	October 5, 1993	Japan			Yes
	27.	JP 09-059159	March 4, 1997	Japan			Yes
	28.	JP 62-123117	June 4, 1987	Japan			Yes
	29.	WO 95/09614	April 13, 1995	WIPO			
	30.	WO 96/33980	October 31, 1996	WIPO			
	31.	WO 96/38131	December 5, 1996	WIPO			
	32.	WO 97/02017	January 23, 1997	WIPO			
	33.	WO 98/38984	September 11, 1998	WIPO			
	34.	WO 98/55148	December 10, 1998	WIPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)	

Examiner	Date Considered
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**Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  <b>PTO Form 1449</b> <b>August 4, 2006</b>				Attorney Docket No. <b>056291-5230-US</b>		Application No. <b>10/565,100</b>	
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	35.	WO 00/00179	January 6, 2000	WIPO			
	36.	WO 00/16776	March 30, 2000	WIPO			Yes
	37.	WO 00/55141	September 21, 2000	WIPO			
	38.	WO 00/56338	September 28, 2000	WIPO			
	39.	WO 00/59475	October 12, 2000	WIPO			
	40.	WO 01/04102	January 18, 2001	WIPO			
	41.	WO 01/47495	July 5, 2001	WIPO			
	42.	WO 01/76586	October 18, 2001	WIPO			
	43.	WO 02/02534	January 10, 2002	WIPO			
	44.	WO 02/06834	January 24, 2002	WIPO			
	45.	WO 02/20020	March 14, 2002	WIPO			
	46.	WO 02/64132	August 22, 2002	WIPO			
	47.	WO 02/65834	August 29, 2002	WIPO			
	48.	WO 02/89773	November 14, 2002	WIPO			
	49.	WO 03/00294	January 3, 2003	WIPO			
	50.	WO 03/017940	March 6, 2003	WIPO			
	51.	WO 03/024426	March 27, 2003	WIPO			
	52.	WO 03/024429	March 27, 2003	WIPO			
	53.	WO 03/024430	March 27, 2003	WIPO			
	54.	WO 03/032956	April 24, 2003	WIPO			
	55.	WO 03/072139	September 4, 2003	WIPO			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	56.	Barker et al. "Studies leading to the identification of ZD1839 (IRESSA): an orally active, selective epidermal growth factor receptor tyrosine kinase inhibitor targeted to the treatment of cancer" Bioorg Med Chem Lett. 11(14): 1911-1914 (2001)					
	57.	Baselga et al. "Phase I safety, pharmacokinetic, and pharmacodynamic trial of ZD1839, a selective oral epidermal growth factor receptor tyrosine kinase inhibitor, in patients with five selected solid tumor types" J Clin Oncol. 20(21): 4292-4302 (2002)					
	58.	Berger et al. "Supersaturation of sulfates in electrodialysis" Ind. Eng. Chem., Process Design Develop. 1: 229-236 (1962) Abstract					
	59.	Brewster et al. "A Novel Cyclodextrin-containing Glass Thermoplastic System (GTS) for Formulating Poorly Water Soluble Drug Candidates: Preclinical and Clinical Results" Journal of Inclusion Phenomena and Macrocyclic Chemistry 44(1-4): 35-38 (2002)					
	60.	Capello et al. "Percutaneous penetration of Ibuprofen from supersaturated solutions" Acta Technologiae et Legis Medicamenti XIII(1): 25-35 (2002) (Translation enclosed)					
Examiner		Date Considered					
<b>Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Class</b>	<b>Sub-Class</b>	<b>Translation</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	61.	Espinoza "Influence of admixed citric acid on the release profile of pelanserin hydrochloride from HPMC matrix tablets" Int J Pharm. 201(2):165-173 (2000)					
	62.	Hasegawa et al. "Supersaturation mechanism of drugs from solid dispersions with enteric coating agents" Chem Pharm Bull (Tokyo) 36(12): 4941-4950 (1988)					
	63.	Herbst et al. "Selective oral epidermal growth factor receptor tyrosine kinase inhibitor ZD1839 is generally well-tolerated and has activity in non-small-cell lung cancer and other solid tumors: Results of a phase I trial" J Clin Oncol 20(18): 3815-3825 (2002)					
	64.	Iervolino et al. "Membrane penetration enhancement of ibuprofen using supersaturation" Int. J. Pharm. 198: 229-238 (2000)					
	65.	Iervolino et al. "Penetration enhancement of ibuprofen from supersaturated solutions through human skin" Int. J. Pharm. 212: 131-141 (2001)					
	66.	Ikeda et al. "Effect of hydrophobically-modified hydroxypropyl methylcellulose on the crystallization from supersaturated solutions of indomethacin" Chem. Pharm. Bull. 42(11): 2320-2326 (1994)					
	67.	Lawrence et al. "Small-molecule tyrosine kinase inhibitors as radiosensitizers" Seminars in Radiation Oncology 12(3): 33-36 (2002)					
	68.	Loftsson et al. "The effect of water-soluble polymers on aqueous solubility of drugs" Int. J. Pharm. 127: 293-296 (1996)					
	69.	McKillop et al. "Cytochrome P450-dependent metabolism of gefitinib" Xenobiotica 35(1): 39-50 (2005)					
	70.	McKillop et al. "Metabolic disposition of gefitinib, an epidermal growth factor receptor tyrosine kinase inhibitor, in rat, dog and man" Xenobiotica 34(10): 917-934 (2004)					
	71.	Megrab <i>et al.</i> "Oestradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation" J. Control Rel 36: 277-294 (1995)					
	72.	Moser et al. "Stabilization of supersaturated solutions of a lipophilic drug for dermal delivery" Int. J. Pharm. 224: 169-176 (2001)					
	73.	Munday "Film coated pellets containing verapamil hydrochloride: enhanced dissolution into neutral medium" Drug Development and Industrial Pharmacy 29(5): 575-583 (2003)					
	74.	N Magné et al. "Sequence-dependent effects of ZD1839 ('Iressa') in combination with cytotoxic treatment in human head and neck cancer" British Journal of Cancer 86: 819-827 (2002)					
	75.	Nakagawa et al. "Phase I pharmacokinetic trial of the selective oral epidermal growth factor receptor tyrosine kinase inhibitor gefitinib ('Iressa', ZD1839) in Japanese patients with solid malignant tumors" Ann Oncol. 14(6): 922-930 (2003)					
	76.	Neiman et al. "Separation of a highly dispersed fraction in supersaturated solutions during formation of calcium sulfate precipitates" Kolloid. Zh. 35(4): 781-783 (1973) Abstract					
	77.	Pellett <i>et al.</i> "The penetration of supersaturated solutions of piroxicam across silicone membranes and human skin in vitro" J. Control Release 46: 205-214 (1997)					
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